

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-0237 MDL No. 2327
THIS DOCUMENT RELATES TO: <i>Berry, et al. v. Ethicon, Inc., et al.</i> Case No.: 2:12-cv-03074 <i>Booher, et al. v. Ethicon, Inc., et al.</i> Case No.: 2:12-cv-3076 <i>Mattingly v. Ethicon, Inc., et al.</i> Case No.: 2:12-cv-03097 <i>Ludwig v. Ethicon, Inc., et al.</i> Case No.: 2:12-cv-03093	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS’ OPPOSITION IN RESPONSE TO DEFENDANTS’ MOTION TO
EXCLUDE GENERAL-CAUSATION OPINION TESTIMONY OF
KONSTANTIN WALMSLEY, M.D.**

I. INTRODUCTION

Dr. Konstantin Walmsley (“Dr. Walmsley”) is a board certified urologist licensed to practice in the United States. *See* Ex. A, Walmsley CV at 1. Dr. Walmsley regularly evaluates and treats stress urinary incontinence in his clinical practice. *See* Ex. B, Walmsley Berry Rpt. at 1; Ex. C, Walmsley Booher Rpt. at 1; Ex. D, Walmsley Mattingly Rpt. at 1; Ex. E, Walmsley Ludwig Rpt. at 1. He has clinical experience with a variety of options to treat SUI – including mid urethral slings (synthetic and non-synthetic) and autologous fascial slings. He has both reviewed medical literature and attended training provided by Ethicon on mid-urethral slings and has explanted and

performed revision procedures on mid-urethral slings. *See e.g.*, Ex. B, Walmsley Berry Rpt. at 1-2. Dr. Walmsley applied his clinical experience and review of the literature to form the opinions Defendants take issue with. These opinions rest on a reliable foundation of clinical experience bolstered by references to medical literature.

Dr. Walmsley's two general opinions, presented in his case-specific reports, are as follows: (1) the risks associated with the TVT device at issue were not sufficiently addressed in that device's Instructions for Use ("IFU") at the time plaintiff was implanted; and (2) there were safer alternative procedures available to treat stress urinary incontinence in women, including the autologous fascial sling. *See* Ex. B, Walmsley Berry Rpt. at 7-9; Ex. C, Walmsley Booher Rpt. at 4-6; Ex. D, Walmsley Mattingly Rpt. at 4-6; Ex. E, Walmsley Ludwig Rpt. at 4-6.

Dr. Walmsley's General Opinion No. 1 and General Opinion No. 2 are both reliable, relevant to this litigation, and within his expertise. Therefore, both opinions should be admitted and Defendants' motion should be denied.

II. LEGAL STANDARD

Pursuant to Federal Rule of Evidence 702, "expert testimony is admissible if the expert is 'qualified...by knowledge, skill, experience, training, or education,' and if his testimony is (1) helpful to the trier of fact in understanding the evidence ...; (2) based on sufficient facts or data; and (3) the product of reliable principles and methods that (4) have been reliably applied to the facts of the case." *Carlson v. Boston Scientific Corp*, 2015 1931311 at * 2 (S.D.W.Va). A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993).

This Court has held that a practicing urologist may offer expert testimony regarding the specific risks of implanting mesh products consistent with those at issue in the instant matter and

whether the relevant IFU sufficiently identified those risks. *See, e.g., Wise v. C. R. Bard, Inc.*, No. 2:12-cv-01378, 2015 U.S. Dist. LEXIS 14869, at *16 (S.D. W. Va. Feb. 7, 2015) (allowing urologist to opine regarding risks posed by implanted mesh product and whether the relevant risks were identified in the implanted product’s IFU).

This Court has previously considered Dr. Walmsley’s opinions regarding safer procedures and mesh complications in the context of the Pinnacle device. *See Eghnayem v. Boston Scientific Corp.*, 57 F.Supp.3d 658, 714-715 (S.D.W.Va. 2014). This Court found “simply because Dr. Walmsley believes that polypropylene mesh devices are functional products does not mean he cannot opine that there were safer alternatives.” *Id.* at 715. Regarding Dr. Walmsley’s opinions on mesh complications in *Eghnayem*, the Court found where his opinions were bolstered by references to scientific literature they were reliable. *Id.* at 714.

Dr. Walmsley’s proffered opinions on IFU adequacy and surgical alternatives rest on a reliable foundation of clinical experience bolstered by literature. Further, these opinions will assist the jury in this case.

III. ARGUMENTS AND AUTHORITIES

A. Dr. Walmsley’s Opinions Regarding the Relevant IFU are Reliable, Relevant to this Litigation, and Within his Expertise.

The sole issue identified by Defendants is whether Dr. Walmsley is qualified to opine regarding “product labeling requirements or the development of warning labels.” Defendants’ Memorandum in Support of Motion to Exclude General-Causation Opinion Testimony of Konstantin Walmsley, M.D. at 4. However, this is a non-issue. Dr. Walmsley will not be asked to offer such opinions.

Defendants cite *Wise v. CR Bard Inc.* for the sound but irrelevant holding that additional expertise – including experience with product labeling requirements – is required to testify about

what should or shouldn't be in an IFU *under law*. But Defendants fail to inform this Court that *Wise* further held that "an experienced urogynecologist may testify about the risks he perceives that the [implanted mesh product] poses to patients and then opine that the [implanted mesh product's] IFU did not convey those risks." *Wise v. C. R. Bard, Inc.*, 2015 U.S. Dist. LEXIS 14869 at *42.

This court has repeatedly allowed expert testimony regarding important risks and whether or not such risks are included in the IFU. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 2014 U.S. Dist. LEXIS 92317 *2 (S.D. W. Va. 2014) (confirming that a urologist is qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's IFU); *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316 at *23 (S.D. W. Va. July 8, 2014) (denying defendant's motion to exclude testimony where an expert urologist is qualified to testify generally on the adequacy of the TVT-O's product warnings and marketing materials.); *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 U.S. Dist. LEXIS 145522, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) (denying defendant's motion to exclude testimony, ruling that "[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings") [*In re Diet Drugs \(Phentermine, Fenfluramine, Dexfenfluramine\) Prods. Liab. Litig.*, MDL 1203, 2000 U.S. Dist. LEXIS 9037, 2000 WL 876900, at *11 \(E.D. Pa. June 20, 2000\)](#) (denying defendant's motion to preclude an expert witness' opinions comparing facts in evidence with the status of the content shown on the product label.)

Here, Dr. Walmsley will be testifying about the risks posed by the implanted mesh product and will opine that the IFU did not adequately convey those risks. Based on his medical knowledge and clinical experience with the risks of mesh products, he will testify as to whether the IFU was

sufficient for the purposes of fully informing patients of all relevant risks. Dr. Walmsley is not being produced to testify as to whether or not warning labels should be required, by law, to include these risks. Defendants' attempt to exclude Dr. Walmsley's relevant, reliable, and expert testimony by expanding its scope beyond its intended boundaries is misguided, and incorrectly interprets this Court's prior rulings.

As a practicing urologist experienced using mesh and non-mesh slings to treat stress urinary incontinence, Dr. Walmsley is sufficiently qualified to testify about the associated risks of these products and the adequacy of warnings contained in the relevant IFUs. Therefore, Defendants' motion must be denied.

B. Dr. Walmsley's Opinion on Safer Alternative Procedures Is Relevant and Admissible.

Defendants concede that "this court has generally reserved ruling on whether an expert's 'safer-alternative procedure' opinion is relevant to a claim for design defect, preferring instead to address the relevancy of this opinion in the individual cases and in context during trial." Memorandum in Support of Motion to Exclude General-Causation Opinion Testimony of Konstantin Walmsley, M.D. at 5.

Nonetheless, Defendants contend that this Court should abandon its consistent holdings in this regard and prematurely exclude Dr. Walmsley's testimony. Tellingly, Defendants fail to cite a single case from the State of West Virginia or the Fourth Circuit in support of what would result in a significant reversal of precedent. This is a question for trial since this Court has reserved ruling on the question, and has instead addressed the relevancy of an expert's opinion on an individual case-by-case basis, applying the appropriate substantive state law. *See Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *49.

The Southern District of West Virginia has not yet ruled on whether testimony for a safer alternative procedure, rather than an alternative medical device, is relevant for a design defect claim. Further, Defendants' contention that Plaintiffs are forbidden to discuss any safer alternative procedures fails to consider the various issues to which such evidence is relevant, including: (1) the risk-benefit analysis; (2) Ethicon's reasonableness in putting these devices on the market; and (3) punitive damages.

Therefore, this Court should reserve ruling on this issue to allow the trial court to assess this testimony pursuant to relevant state law. In the alternative, at the very least, Plaintiffs should be permitted to call Dr. Walmsley to opine on the existence of safer alternative procedures in the context of risk-benefit analysis, general negligence, and punitive damages.

IV. CONCLUSION

For the reasons above, and more fully set forth in the individual response in the *Booher* and *Ludwig* cases, Defendants Motion to Exclude the Opinions and Testimony of Dr. Walmsley should be denied.

Dated: October 11, 2016

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Rick Barreca
Attorney for Plaintiffs